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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,260	02/23/2004	Warren Shapiro	Premier US-2	8880
7590 12/14/2006				
Dahl & Osterloth, LLP Suite 3405 555 17th Street Denver, CO 80202-3937		EXAMINER LILLING, HERBERT J		
		ART UNIT 1657 PAPER NUMBER		

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/785,260

Applicant(s)

SHAPIRO ET AL.

Examiner

HERBERT J. LILLING

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on NOVEMBER 21, 2006
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15, 19-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 11-15, 19-26 and 28-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The **finality of the previous office action has been rescinded.**
2. The response filed November 21, 2006 is acknowledged and the response to the previous office was persuasive to remove the finality.
3. Claims 11-15, 19-26 and 28-32 are present in the instant application.
4. Claim 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention commensurate in scope with the claimed inventions. The expression "**root extract**" does not define the ingredient(s).

The enablement as well as the written description of the instant specification lack support for the claimed "**root extract**".

The specification lacks adequate written description for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

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invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, that is the "extract", is not a description of that material.

Thus, Claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by complete structure or identifying characteristics, thus the description requirement has not been satisfied, see *Eli Lilly*, 119 F. 3d 1559, 43 USPQ2d 1398 (Fed. Cir 1997).

Applicant has argued that the following:

"The test for definiteness is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v.*

Safety Travel Cha, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986), and see MPEP 2173.02 Clarity and Precision [R-3] - 2100 Patentability. All that need be understood by skilled artisans is that the claim covers root extracts of *Kaempferia Galanga*. This is a definite plant root, definitively extracted. A skilled artisan would understand that any extract from this root falls within the claims. Therefore, the term "extract" in the claims is not vague or indefinite.

Furthermore claim 14 specifically states that the root extract of *Kaempferia Galanga* comprises ethyl p-methoxycinnamate. Applicants submit that the term "extract" and its further definition in the disclosure and in claim 14 is definite for at least the above reasons and further because it more specifically further limits to ethyl p-methoxycinnamate. Accordingly, Applicants respectfully

request that the Examiner reconsider and withdraw the rejection of claims 11-15, 19-25, and 31, and respectfully request that the claims be allowed.

The scope of the expression "root extract of Kaempferia Galanga" encompasses a great number of compounds that exists in the extraction of this plant material. However, the number of extracts far exceeds the one specific compound that is extracted from the plant material which is the only compound listed in the specification. The specification is considered to be totally inadequate in describing the scope of possible compounds extracted from the plant material. In view of the lack of a suitable written description of the invention containing the claimed subject matter which subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention drawn to the expression "root extract". This is supported by the fact that at least the following compounds were found to be extracted from the plant material from the "root extract of Kaempferia Galanga":

1. borneol
2. camphene
3. carene
4. 3-Carene borneol
5. 1,8-cineole
6. cinnamic acid ethyl ester
7. ethyl p-methoxycinnamate
8. isoamyl p-methoxycinnamate

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9. n-pentadecane
10. p-methoxycinnamic acid ethyl ester
11. p-methoxycinnamic acid methyl ester
12. p-methoxystyrene

A computerized West search of the above compounds yielded a total of 9707 hits which are possible anticipatory art when combined with any composition having the compound is within the percentage of up to about 5% in the composition(s). However, the extract per se can be any other compound or compounds that would be possible from an extraction using different extractants since the specification lacks sufficient information pertaining to the scope of the extraction method as well as the scope of the term "root extract" for the components in the extract per se.

Search Results -

Terms	Documents
(borneol or camphene or carene or 3-Carene borneol or 1,8-cineole or cinnamic acid ethyl ester or ethyl p-methoxycinnamate or isoamyl p-methoxycinnamate or n-pentadecane or p-methoxycinnamic acid ethyl ester or p-methoxycinnamic acid methyl ester or p-methoxystyrene)	9707

Database:

US Pre-Grant Publication Full-Text Database
US Patents Full-Text Database
US OCR Full-Text Database
EPO Abstracts Database
JPO Abstracts Database
Derwent World Patents Index
IBM Technical Disclosure Bulletins

Search:**Refine Search****Recall Text**

Search History

DATE: Saturday, December 02, 2006 Purge Queries Printable Copy Create Case

<u>Set Name</u> side by side	<u>Query</u>	<u>Hit Count</u>	<u>Set Name</u> result set
	<i>DB=PGPB,USPT,EPAB,JPAB,DWPI,TDBD; PLUR=YES; OP=ADJ</i> (borneol or camphene or carene or 3-Carene borneol or 1,8-cineole or cinnamic acid ethyl ester or ethyl p-methoxycinnamate or isoamyl p-methoxycinnamate or n-pentadecane or p-methoxycinnamic acid ethyl ester or p-methoxycinnamic acid methyl ester or p-methoxystyrene)	9707	L1

The instant specification has been found to be totally defective with respect to the written specification as well as to the enablement commensurate in scope with the expression. All that need be understood by skilled artisans is that the claim covers root extracts of Kaempferia Galanga. This is a definite plant root, definitively extracted. A skilled artisan would understand that any extract from this root falls within the claims. Therefore, the term "extract" in the claims is not vague or indefinite.

The argument that "The test for definiteness is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification."; however, one skilled in the art would consider the instant specification as being totally defective as well as incomplete with the claimed subject matter.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The term "extract" renders claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31, vague and indefinite in scope as to the structure(s) or compound(s) within the composition. The term "extract" is a processing condition that depends upon the method which term "extract" will change as the conditions changes in the processing of the root extract. Applicant is require to indicate in the claims (a) the structure of the ingredient(s) or (b) the compound(s) and the number of compound(s) effective for the claimed composition or a sufficient number of physical data to define the compound(s) or to submit a product-by-process for claimed "root extract".

The arguments have been deemed not to be persuasive with respect to:

Moreover, the use of the term "extract" is common in patent lexicography relating to derivatives of organic matter, as evidenced by the patents and prior art listed in the brief summary of the invention section of the initial patent filing. Use of the term "extract" does not render the claims of a patent indefinite or vague, as often the term "extract" is the most accurate and complete means of describing a constituent and essential ingredient of the claimed invention.

The term "extract" is not definitive of any specific compound and does not define structures, physical or chemical properties of compounds and is only descriptive of a

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process step(s). The language of the claims must make it clear what subject matter the claims encompass to adequately delineate there "metes and bounds". The courts have indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. Thus, at least claims 11, 12, 13, 15, 19, 20, 21, 23, 24, 25, 30, and 31, fail to comply with the above requirements.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 11, 12, 14, 15, 19, 20, 21, 22, 24, 25, 26, 28, 30, 31 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by Voss, U.S. 5,972,315 in view of Example 1b, wherein the concentration of the ethyl p-methoxycinnamate is 2%. The claims do not exclude the components of the reference and the additive is an extract of. Any extract may be employed in the broad composition obtained from the root of Kaempferia Galanga.

The arguments pertain to the reference composition:

" Furthermore, the only mention of ethyl p-methoxycinnamate in Voss is in col. 4, line 47. The inclusion of ethyl p-

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methoxycinnamate, to the extent it is mentioned in this one instance, is as a UV B filter in the amount of 2.0 g in a total emulsion of 100 g. Voss limits inclusion of, ethyl p-methoxycinnamate to this one Example 1b, and furthermore, limits the role of ethyl p-methoxycinnamate to the role of a UV B filter at a 2.0% concentration. By such limitation, Voss teaches away from use of ethyl p-methoxycinnamate as anything but a UV B filter in a 2.0% concentration. Applicant's compositions use of ethyl p-methoxycinnamate serves an entirely different function than the Voss composition. Applicant's composition is claimed only in use of ethyl p-methoxycinnamate as protection against the harmful effects of tyrosinase or chemically induced irritation and specifically does not include use of ethyl p-methoxycinnamate for protection against UV radiation.”;

has been considered but the claims are drawn to compositions which are within the scope of the claimed subject matter. The claimed functional language for the same product is not patentable in the absence of a showing of difference with respect to the components in the composition(s). A new use of an old composition does not render the composition patentable, see the following:

It is well settled that if a reference reasonably teaches a product which is identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977).

B. Claims 11, 12, 13, 14, 15, 19, 20, 21, 22, 23, 24, 25, 26, 28, 30, 31 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by JP40815734 (June 18, 1996) in view of paragraphs 26, 29, 31, 41-43 and 49 which contains extracts of the claimed plant material within the scope of the claimed percentages.

C. Claims 11, 12, 13, 15, 19, 20, 21, 23, 25, and 31 are rejected under 35 U.S.C. 102(b) as anticipated by Schade, DE19849514, May 04, 2000, which reference teaches isoamyl p-methoxycinnamate which is within the scope of the claimed inventions.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 13, 23, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, U.S. 5,972,315 in view of Example 1b, wherein the concentration of the ethyl p-methoxycinnamate is 2% further in view of the disclosure which teaches that the percentage range is as low as 0.1% which would have been prima facie obvious to one of ordinary skilled in the art to employ absent unexpected or unobvious results.

B. Claims 11-15, 19-26 and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP40815734 (June 18, 1996) which abstract discloses extracts of the claimed plant material, see paragraphs 21-23, 26, 29, 31, 36, 37, 41-43 and 49 which extracts are prima facie in view of the broad disclosure as noted by the abstract as well as the examples noted in the above paragraphs which extracts contain at least the ethyl p-methoxycinnamate in the extract.

8. **No claim is allowed.**

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9. It is noted that technically the claims were previously rejected under second paragraph of 35 USC 112 in the first office action and the same claims were rejected under the same paragraph which was not the grounds for removing the finality. The updated search resulted in the findings of new art which also is not the grounds for removing the finality. The rejection based on 35 USC 112 first paragraph is a new ground of rejection which necessitated the removal of the final rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit **1657**
December 04, 2006



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